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49. (New) The process of claim 48, wherein the elevated temperature is about the reflux temperature of the organic solvent.
50. (New) The process of claim 46, wherein the dissolving step comprises refluxing the organic solvent.
51. (New) The process of claim 46, wherein the adding step comprises adding water dropwise to the solution.
52. (New) The process of claim 46, wherein the precipitating step comprises cooling the solution to about 10 °C.
53. (New) The process of claim 47,  
wherein the dissolving step comprises refluxing the organic solvent;  
wherein the adding step comprises adding water dropwise to the solution;  
wherein the precipitating step comprises cooling the solution to about 10 °C; and  
wherein the drying conditions comprise heating the precipitated mirtazapine to the reflux temperature of the organic solvent under reduced pressure.
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#### REMARKS

The foregoing claim amendments were not entered when submitted on July 11, 2002, under 37 CFR § 1.116. Therefore, claims 29-45 are currently pending in the application. Entry of the foregoing amendments is respectfully requested. Upon entry of the amendments, claims 30-35, 37-41, and 46-53 will be pending.

Applicants have also amended the specification to add a claim of priority to a second provisional application.

Applicants' undersigned attorney will contact the Examiner shortly to request and arrange an interview.

In view of the foregoing amendments and the remarks of record, Applicants respectfully request allowance of the pending claims. The Examiner is invited to contact the undersigned attorney regarding any matter concerning the pending application.

Respectfully submitted,

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## MARKED-UP VERSION OF AMENDMENTS

### IN THE SPECIFICATION:

This application claims the benefit of U.S. provisional Application Serial No. 60/130,047, filed April 19, 1999, and U.S. provisional Application Serial No. 60/182,745, filed February 16, 2000.

### IN THE CLAIMS:

30. [The] A crystalline adduct of mirtazapine and water [of claim 29] containing up to about three weight percent water.
31. [An] The adduct of mirtazapine and water of claim 30 prepared by precipitation from a solvent comprising water and either an alcohol or acetone.
37. A[n] crystallized adduct of mirtazapine and water prepared by:
1. slow addition of water at elevated temperature to a mixture of mirtazapine and an organic solvent selected from the group consisting of alcohols and acetone,
  2. precipitating the adduct by cooling, and
  3. separating the adduct from the water and organic solvent.]
- i) crystallizing mirtazapine from a solution comprising water;
- ii) recovering crystallized mirtazapine; and
- iii) drying the crystallized mirtazapine until the crystallized mirtazapine contains up to about 3 percent water.
38. The adduct of mirtazapine and water of claim 37 wherein the [organic solvent is] solution also comprises an alcohol.
41. The adduct of mirtazapine and water of claim 40 wherein [from about one to about four volumes of water are added relative to the amount of ethanol] the solution comprises a ratio of ethanol:water ranging from about 1:1 to about 1:4.